6

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/917,381	07/27/2001	Jeffrey Joseph Stewart		9969

7590 06/02/2006

Jeffrey J. Stewart
2205 E 17th
Spokane, WA 99203

EXAMINER	
CHENCINSKI, SIEGFRIED E	

ART UNIT	PAPER NUMBER
3628	

DATE MAILED: 06/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 10/03)

Office Action Summary	Application No.	Applicant(s)	
	09/917,381	STEWART, JEFFREY JOSEPH	
	Examiner	Art Unit	
	Siegfried E. Chencinski	3628	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 July 2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

1. **Claims 1-20 are rejected under 35 U.S.C. 101** because the claimed invention is directed to non-statutory subject matter. Claims 1-20 are not directed to any one of the areas of patentable subject matter, such as product, process, process of making or composition.

For a claim to be statutory under 35 USC 101 the following two conditions must be met:

1) In the claim, the practical application of an algorithm or idea results in a useful, concrete, tangible result,

AND

2)The claim provides a limitation in the technological arts that enables a useful, concrete, tangible result.

According to the above guidelines, Applicant's claims are limited to the manipulation of abstract ideas in the context of patentability.

Applicant is advised to satisfy the statutory requirements for the claims. Applicant is also advised not to add any new matter to the specification or the claims.

2. **Claims 1-20 are rejected under 35 U.S.C. 101** because the claimed invention is not supported by either a novel asserted utility or a well established utility.

Applicant asserts in the Summary of the Invention section of the specification that "an object of the present invention is to provide a novel financial security for the financing of pharmaceutical R&D" (Page 10, lines 22-24). However, Applicant fails to

claim limitations in independent claims 1, 10 and 11 which relate to the provision of financial securities. Instead, Applicant merely claims equations for valuing investment project expenditures based on estimated future streams of pharmaceutical project expenditures and the related detailed steps for defining and quantifying the variables making up the equations. Further, Applicant's disclosure fails to contain descriptive material relating to the provision of financial securities by only containing methods of financially valuing investment project expenditures based on estimated future streams of pharmaceutical project expenditures.

3. **Claims 11-20 are rejected under 35 U.S.C. 101** because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966). Claim 11 claims a financial security by merely reciting a method of valuing a pharmaceutical R&D cash flow without setting forth any steps involved in the process of establishing and providing a financial security.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. **Claims 1-20 is also rejected under 35 U.S.C. 112, first paragraph.** Specifically, since the claimed invention is not supported by either a novel asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. As stated in the rejection of Applicant's claimed invention under the provisions of 35 U.S.C. 101 Applicant's specification fails to contain descriptive material relating to the provision of financial

securities by only containing methods of financially valuing investment project expenditures based on estimated future streams of pharmaceutical project expenditures. Valuation methods and related algorithms for valuing prospective expenditures and cash flows are not statutory inventions, and also are not financial securities.

5. **Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph,** as based on a disclosure which is not enabling. Clear guidelines and boundaries for the variable R, the project risk and project phase risk measure, critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). whether R sub 0 or R sub n, are absent from the disclosure, both in the specification and in the claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. **Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph,** as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) Applicant asserts in the Summary of the Invention section of the specification that "an object of the present invention is to provide a novel financial security for the financing of pharmaceutical R&D" (Page 10, lines 22-24). However, Applicant fails to claim limitations in independent claims 1, 10 and 11 which relate to the provision of financial securities. Instead, Applicant merely claims equations for valuing investment project expenditures based on estimated future streams of pharmaceutical project expenditures and the related detailed steps for defining and quantifying the variables making up the equations. Further, Applicant's disclosure fails to contain descriptive material relating to the provision of financial securities by only containing methods of financially valuing investment project expenditures based on estimated future streams of pharmaceutical project expenditures.

7. **Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph,** as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: the needed limits and guidelines for the variables R sub 0 and R sub y. The current definitions in the claim fail to enable ordinary practitioners of the art to replicate the calculations and obtain a consistent result for the same project if they were to do the calculations independently from each other. Further, the specification does not provide sufficient guidelines to even obtain Applicant's calculational results for at least Example 1 which the examiner attempted to calculate, without investing in burdensome experimentation.

8. **Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph,** as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: a novel financial security for the financing of pharmaceutical R&D, as stated in the Summary of the Invention section of the specification (Page 10, lines 22-24).

9. **Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph,** as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant claims to have invented a novel financial security for the financing of pharmaceutical R&D, as stated in the Summary of the Invention section of the specification (Page 10, lines 22-24), and in claim 11. However, there is no evidence in the disclosure that Applicant had actually had possession of the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 1-5 10, 11, 18 & 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martin, Petty, Keown and Scott, Basic Financial Management, 5th Ed., 1991, Prentice Hall (hereafter Martin) in view of Weiss (Introductory Statistics, Fifth Edition, Addison Wesley Longman, Inc., March 1999) and Horrigan et al. (US Patent 6,493,682 B1, hereafter Horrigan).

Re. Claim 1, Martin discloses a method of estimating the value of a proposed investment at various points in time, which includes the value at the time of the investment (time zero), as part of a textbook which teaches the building blocks of the mathematics of finance.

Applicant has restated the well known financial equations for present project valuation into one equation which can be used to calculate value at any milestone of a proposed project in certain time increments, such as yearly, beginning at time zero.

The equation contains the following elements:

- A summation feature of adding up each time period's value through the last project period (year n);
- Two sub component equations for each time increment for income and expenses (I & E); and
- Two discount factors for the value of cash for each time segment, (a) representing a basic cost of capital (k for discount rate) and, (b) a risk mitigation factor R to represent the differing estimated risk levels in each project phase (R sub 0 through n to match each risk phase).

Applicant's version of this valuation technique remains unchanged from the textbook concepts and equations in spite of different representations of the same equations. Martin builds up to the final risk mitigation by beginning with the risk free cost of capital, then introducing a firm's own general cost of capital, and finally adding the specific risk factor related to a given project.

Martin discloses a generic version of the discounted cash flow equation on page 109,

line 3 – page 110, line 21 (Summary of the General Valuation Process and equation 4-10, with notes). Here income and expenses are netted out through a combined variable C (cash flow).

It would have been obvious to those with ordinary skill in the art at the time of Applicant's invention that Applicant's claimed equation for estimating the value of expected future pharmaceutical R&D cash flow is merely a specific application of equations used in the financial arts and specifically taught by Martin in his textbook.

Next, Weiss discloses Applicant's conditional probability equation on page 240, line 2 of his textbook. Further, the use of conditional probability equations was well established in the financial arts at the time of Applicant's invention. For example, Horrigan discloses the use of conditional probability analysis in the investment art (Col. 22, l. 33). The fact that conditional probability art has various detailed equations would have been obvious to the ordinary practitioner, since he would have known that he only had to look them up in textbooks or perhaps even on the world wide web.

Therefore, it would have been obvious to the ordinary practitioner of the art at the time of Applicant's invention to have combined the basic teachings of Martin with the teachings of Weiss and Horrigan to adapt basic techniques of the financial art to the application of valuing financing proposals for pharmaceutical R&D projects using estimated (pro forma) cash flows through all the phases of the project from inception through the estimated completion of the project's revenue phase. The motivation would have been to bring to bear the resources and best practices of financial institutions to fund pharmaceutical R&D investments, modeled after the purposes and practices of finance presented by Martin's textbook where the objective of finance is presented to be to raise funds for investment by a non financial company from the financial markets through institutions and procedures (Martin, p. 25, l. 7-8).

Re. Claim 2, Martin uses different mathematical symbols which have the same meaning as those used by applicant's invention. As per the rejection of claim 1, Martin teaches and suggests the equivalent of time 0 is the present time and where $V_{\circ}$ $_{(Vsub0)}$ is the risk-adjusted net present value of a pharmaceutical R&D cash flow.

Re. Claim 3, as per the rejection references in Martin's textbook in claim 1, Martin discloses,

suggests and implies that estimated future project income sources can be based on various sources, including project sales revenue.

Re. Claim 4, as per the rejection references in Martin's textbook in claim 1, Martin discloses, suggests and implies that estimated future project expense sources can be based on various sources, including the project's estimated manufacturing expenses.

Re. Claim 5, Martin discloses the risk-free interest rate in numerous places in the context of equations to value an investment project. This is the rate for US government bonds. One place is in chapter 7, page 277, line 12.

Re. Claim 10, Martin discloses a method of estimating the value of a debt with a coupon rate issued on an anticipated future cash flow, including the consideration of project risk see the rejections of claims 1 and 11). Weiss discloses a variety of probability calculation techniques and related equations (see the rejection of claim 1 and 11). Horrigan teaches the application of probability techniques in the financial investment arts (see the rejection of claims 1 and 11). Neither Martin, Weiss or Horrigan explicitly disclose Applicant's particulars of estimating the value, at time 0, of a debt issued on a pharmaceutical R&D cash flow, said method comprising calculating V_o in accordance with the equation: $V_o=R_oF\ (1+q-w)\}^y$, where R_o is the risk mitigated at time 0, F is the face value of said debt, q is interest rate of said debt, w is the risk-free interest rate, y is the time said debt is due to be repaid, and R_oF is the discount price. However, it is implicit in Martin that Martin's teachings apply to all kinds of financings and valuations thereof, including pharmaceutical R&D projects, and the ordinary practitioner of the art at the time of Applicant's invention would have seen that as obvious. Also, Applicant's equation contains the risk mitigation variable for the project as a whole, which is readily suggested by both Martin and Weiss. Further, the equation in this claim is related to the equation in claim 11, with the difference being the coupon. Therefore, it would have been obvious to the ordinary practitioner of the art at the time of Applicant's invention to have combined the basic teachings of Martin with the teachings of Weiss and Horrigan to adapt basic techniques of the financial art to the application of valuing financing proposals for pharmaceutical R&D projects using estimated (pro forma) cash flows through all the phases of the project from inception through the estimated completion of the project's

revenue phase. The motivation would have been to bring to bear the resources and best practices of financial institutions to fund pharmaceutical R&D investments, modeled after the purposes and practices of finance presented by Martin's textbook where the objective of finance is presented to be to raise funds for investment by a non financial company from the financial markets through institutions and procedures (Martin, p. 25, l. 7-8).

Re. Claim 11, Martin discloses a method of estimating the value of a debt security issued on an anticipated future cash flow, including the consideration of project risk (see the rejection of claim 1). Weiss discloses a variety of probability calculation techniques and related equations (see the rejection of claim 1). Horrigan teaches the application of probability techniques in the financial investment arts (see the rejection of claim 1). Martin does not explicitly disclose Applicant's version of a financial security comprising a debt issued at time 0 on a pharmaceutical R&D cash flow, said security comprising a face value, at least one default term, an interest rate, at least one repayment term, and a discount price, where said discount price D is calculated in accordance with the equation D=RoF, where Ro is the risk mitigated at time 0, and where F is said face value. The financial profile of Applicant's security fits that of a zero coupon bond.

The Martin textbook discloses the equivalent of Applicant's equation and many variations thereof by developing the subject from the ground up through building blocks, various overviews and many details of the practice of the financial art involving financial debt securities. Martin explains the features, benefits, advantages, disadvantages and interplays between these forms of financing for a firm and how the cost of capital, risk, time, revenue, expense, cash flow, investment, present value, net present value, future value and related factors are considered, estimated and calculated in the art of finance. The zero coupon bond is described on page 720. A zero coupon bond is a bond which pays no interest or dividends during the life of the bond and which is sold at a deep discount to its face value at the time of issuance. The bond holder of a zero coupon bond depends entirely on capital appreciation for his return on investment. Martin discloses an example of such a bond financing on page 720 by way of illustrating a $1,000 zero coupon bond issued in April, 1983 by Homestead Savings at a discount of

$ 750, meaning that the original bond buyer paid $ 250 for this $ 1000 par value bond which matured in 1995. Presuming that the bond was paid at the full face or par value of $ 1,000 at maturity, the original investor who held it for the entire 12 years earned a yield of 11.50 percent per year compounded for the twelve year period. The benefit to the issuer was that they received $ 250 of cash per $ 1000 par value bond, and had no cash outflows for the entire 12 year period by promising to pay back 12 years later 400% (four times) of the original cash received from investors.

Risk is basically the interest rate (or discount rate) which is added to the riskless cost of capital (defined as the equivalent cost of a US government note) to make up the total of the coupon rate and the discount rate. Totals risk is made up of a number of risk components. One way to summarize the risk elements is to categorize risk into two risk elements, the risk of the firm, and project risk. The general risk free cost of capital plus the firm's general risk premium join to form the firm's cost of capital, also known as the discount rate. Applicant's invention presents their discount price formula D in this well known format taught by Martin. Some additional considerations are taught by Martin regarding Applicant's project formulation as follows: Some long term debt only carries a coupon rate, some long term debt only carries a discount rate (zero coupon debt) and some debt carries a combination of the two. It can get more complicated than that, since conversion right, and other instruments can also be combined with the issuance of debt instruments. Martin discloses related equations with notations which differ from those used by Applicant, but these differences are merely superficial. The Martin textbook also discloses the central role played by cash flow in the finances of a company and in the related analysis of future financing risks by all the parties involved (p. 94, l. bottom – p. 96, middle).

Applicant's equation "$D = R_oF$" basically describes the calculation of the discounted price or value of the zero coupon bond described above. In the case of the Homestead Bank example of a zero coupon bond, Applicant's D has a $250 value at the time of issuance, R_o is an approximate annual yield of 11.75% and $ 1000 is the face value of the bond. An example of the equation is presented by Martin on page 143, as $V_b = (I_1/(1+R_b)^1 + \ldots + I_{12}/R_N) + M/(1+R)^N$, where interest payments (I) are zero, M is $ 1,000,

and R_b is approximately 0.1175 (11.75%). With interest payments equaling zero, the equation reduces to $V_b = 0 + M/(1+R)^N$. It is implicit to Martin's disclosure that the financial methodology disclosed in his textbook can be applied to any industry. Therefore, an ordinary practitioner of the art at the time of Applicant's invention would have found it obvious to have used Martin's disclosure to construct a financial security issued on a pharmaceutical R&D cash flow. The motivation would have been to bring to bear the resources and best practices of financial institutions to fund pharmaceutical R&D investments, modeled after the purposes and practices of finance presented by Martin's textbook where the objective of finance is presented to be to raise funds for investment by a nonfinancial company from the financial markets through institutions and procedures (Martin, p. 25, l. 7-8).

Re. Claim 18, Martin discloses convertible debt and that the debt of a firm can be convertible debt (pp. 743-744).

Re. Claim 20 Martin teaches and suggests that the ability to repay debt at the repayment term is estimated from projected net cash flow of the revenue phase (see claims 1 and 11, above).

11. **Claims 6-9 are rejected** under 35 U.S.C. 103(a) as being unpatentable over Martin in view of Weiss and Horrigan as applied to claim 1 above, and further in view of Applicant Admitted Prior Art (hereafter AAPA).

Re. Claims 6-9, Martin does not explicitly disclose

- **Re. Claim 6,** where at least one expense, risk, or the time of a pharmaceutical R&D phase is estimated to be about average.
- **Re. Claim 7,** average expenses for selected pharmaceutical R& D project phases, including a phase 1 clinical trial expense of about \$575,000, a phase 2 clinical trial expense of about \$2,300,000, a phase 3 clinical trial expense of about \$17,250,000, an animal study expense in support of a phase 1 clinical trial of about \$500,000, an animal study expense in support of a phase 2 clinical trial of about \$1,000,000, an animal study expense in support of a phase 3 clinical trial of about \$1,500,000, and an approval-associated expense of about \$1,300,000.

- **Re. Claim 8,** where said average risk Ry is selected from the group consisting of about 10% for a preclinical phase, about 20% for a phase 1 clinical trial phase, about 30% for a phase 2 clinical trial phase, about 67% for a phase 3 clinical trial phase, and about 83% for an approval phase.
- **Re. Claim 9,** where said average time of a pharmaceutical R&D phase is selected from the group consisting of about 6 years for a preclinical phase, about 9 months for a phase 1 clinical trial, about 1.5 years for a phase 2 clinical trial, about 3.5 years for a phase 3 clinical trial, about 1.5 years for an approval phase, and about 10 years for a revenue phase.

However, AARA discloses each of these expenses in the specification's Background section as admitted prior art knowledge on page 1, line 10 – page 5, line 11. Therefore, it would have been obvious to an ordinary practitioner of the art at the time of Applicant's invention to have turned to a finance textbook such as that of Martin to adapt a standard equations for estimating the value at time zero of streams of present and future expenditures and incomes in various renditions and combinations to pharmaceutical R&D risk mitigation scenarios with AAPA information for the values of the expense and income variables. The motivation would have been to bring to bear the resources and best practices of financial institutions to fund pharmaceutical R&D investments, modeled after the purposes and practices of finance presented by Martin's textbook where the objective of finance is presented to be to raise funds for investment by a nonfinancial company from the financial markets through institutions and procedures (Martin, p. 25, l. 7-8).

12. **Claim 12 is rejected** under 35 U.S.C. 103(a) as being unpatentable over Martin in view of Weiss and Horrigan as applied to claim 11 above, and further in view of Kossovsky et al. (US Pg. Pub. 2002/0002523 A1, hereafter Kossovsky).

Re. Claim 12, Martin does not explicitly disclose a security where debt is securitized by intellectual property that, but for license to said intellectual property, the making, using, or selling of said pharmaceutical would infringe upon at least one valid claim of said intellectual property. However, Martin discloses secured debt instruments ("Secured

Long-Term Bonds" (pp. 716)). Kossovsky discloses intellectual property and securitized asset cash flow (page 1, [0009], ll. 1-7). Further, an ordinary practitioner of the art at the time of Applicant's invention would have known that the making, using, or selling of a pharmaceutical which is dependent on a given intellectual property (such as a patent) would infringe upon at least one valid claim of such intellectual property by definition, and that such infringement would need to be permitted by the intellectual property owner's own infringement (actually called use of the rights held by the property), which would be legal, or by the owner's giving permission for someone else to infringe on the intellectual property's rights. Therefore, an ordinary practitioner of the art at the time of Applicant's invention would have found it as obvious to have combined the teachings of Martin, Kossovsky and well known information to have provided a debt securitized by intellectual property related to a pharmaceutical, motivated by a desire to support the efficient and reliable commercial exploitation, licensing or assigning of intellectual property rights (Kossovsky, page 1, [0007]-ll. 1-4; [0008]).

13. **Claims 13-17 are rejected** under 35 U.S.C. 103(a) as being unpatentable over Martin in view of Weiss and Horrigan as applied to claim 11 above, and further in view of AAPA.

Re. Claims 13-17, Martin does not explicitly disclose

Re. Claim 13, said pharmaceutical is at a preclinical phase of development and where said Ro is about 10%.

Re. Claim 14, where said pharmaceutical is at a phase 1 clinical trial phase of development and where said Ro is about 20%.

Re. Claim 15, where said pharmaceutical is at a phase 2 clinical trial phase of development and where said Ro is about 30%.

Re. Claim 16, where said pharmaceutical is at a phase 3 clinical trial phase of development and where said Ro is about 67%.

Re. Claim 17, where said pharmaceutical is at an approval phase of development and where said Ro is about 83%.

However, APPA admits that

Re. Claim 13, Ro is about 10% for pharmaceuticals at a preclinical phase of development.

Re. Claim 14, Ro is about 20% for pharmaceuticals at a phase 1 clinical trial phase of development.

Re. Claim 15, Ro is about 30% for pharmaceuticals at a phase 2 clinical trial phase of development.

Re. Claim 16, Ro is about 67% for pharmaceuticals at a phase 3 clinical trial phase of development.

Re. Claim 17, Ro is about 83% for pharmaceuticals at an approval phase of development.

However, AAPA discloses these limitations in the background section of the specification (p. 1, l. 10 – p. 4, l. 18).

Therefore, an ordinary practitioner of the art at the time of Applicant's invention would have found it as obvious to have combined the teachings of Martin and AAPA to have provided a debt securitized by intellectual property related to a pharmaceutical various phases claimed in the limitations of claims 13-17 (Specification, p. 1, l. 10 – p. 5, l. 11). The motivation would have been to bring to bear the resources and best practices of financial institutions to fund pharmaceutical R&D investments, modeled after the purposes and practices of finance presented by Martin's textbook where the objective of finance is presented to be to raise funds for investment by a nonfinancial company from the financial markets through institutions and procedures (Martin, p. 25, l. 7-8).

14. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Martin in view of Weiss and Horrigan as applied to claim 11 above, and further in view of Barron's Dictionary of Finance and Investment (hereafter Barron's).

Re. Claim 19, Martin discloses the possibility of default on a bond (p. 723, l. 18-19). The possibility and likelihood of such a default is what is implicit to what the risk is, risk being reflected in the discount premium above the risk free premium (the rate of US government debt). Barron's defines default as "failure of a debtor to make timely payments of interest and principle as they come due or meet some other provision of a

bond indenture. In the event of default, bondholders may make claims against the assets of the issuer in order to recoup their principle". (p. 140, default). Thus, Martin and Barron's disclose default on a bond debt, with Barron's defining default as a failure to pay a scheduled debt repayment. Therefore, an ordinary practitioner of the art at the time of Applicant's invention would have found it as obvious to have combined the teachings of Martin and Barron's have provided a debt securitized by intellectual property related to a pharmaceutical various phases claimed in the limitations of claims 13-17. The motivation would have been to bring to bear the resources and best practices of financial institutions to fund pharmaceutical R&D investments, modeled after the purposes and practices of finance presented by Martin's textbook where the objective of finance is presented to be to raise funds for investment by a nonfinancial company from the financial markets through institutions and procedures (Martin, p. 25, l. 7-8).

15. INTERPRETATION OF CLAIMS: The recitation of a method of estimating value of a pharmaceutical R&D cash flow in claims 1, and10 and a financial security comprising a debt issued at time 0 on a pharmaceutical R&D cash flow in claim 11 have not been given patentable weight because the recitations occur in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Conclusion

16. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Siegfried Chencinski whose telephone number is

(571)272-6792. The Examiner can normally be reached Monday through Friday, 9am to 6pm.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Hyung S. Sough, can be reached on (571) 272-6799.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any response to this action should be mailed to:

Commissioner of Patents and Trademarks, Washington D.C. 20231

or (571*)273-8300* [Official communications; including After Final communications labeled "Box AF"]

(571) 273-6792 [Informal/Draft communications, labeled "PROPOSED" or "DRAFT"]

Hand delivered responses should be brought to the address found on the above USPTO web site in Alexandria, VA.

SEC

May 26, 2006

FRANTZY POINVIL
PRIMARY EXAMINER
Au 3628